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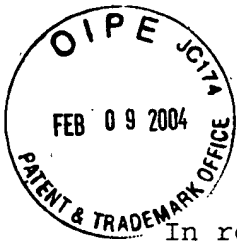
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PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

GULDFELDT et al.

Serial No.: 10/611,812

Group Art Unit: 3762

Filed: July 2, 2003

For: EXTERNAL URINARY CATHETER DEVICE AND A METHOD FOR PRODUCTION THEREOF

CLAIM TO PRIORITY

Commissioner for Patents
P.O. Box 1450
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Sir:

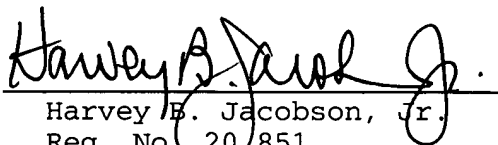
The benefit of the filing date of the prior foreign application filed in the following foreign country is hereby requested and the right of priority provided in 35 U.S.C. §119 is hereby claimed:

Denmark Application No. PA 2001 00735 filed 10 May 2001.

In support of this claim, filed herewith is a certified copy of said foreign application.

Respectfully submitted,

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Kongeriget Danmark

Patent application No.: PA 2001 00735
Date of filing: 10 May 2001
Applicant: Coloplast A/S
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DK-3050 Humlebæk
Denmark

Title: An external urinary catheter device for the relief of male urinary incontinence.

IPC:

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.



Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

8 September 2003

Pia Høybye-Olsen

Title

An external urinary catheter device for the relief of male urinary incontinence.

5 Introduction

The present invention relates to an external urinary catheter device for the relief of male urinary incontinence, comprising a contact member which is adapted to be engaged with at least the extreme portion
10 of a penis; an opening formed in a distal end section of the contact member and positioned substantially opposite the urethral orifice in the position of use, and a discharge conduit connected with the opening to provide a sealed urine flow passage extending in a
15 substantial axial direction towards the exterior of the catheter device. The invention also pertains processes for manufacture of an external urinary catheter device for the relief of male urinary incontinence as well as uses of catheters of this kind.

20

Background art

For the relief of male urinary incontinence external catheters are generally used in the form of condom-like tubular sheaths to be placed externally on
25 penis and having a discharge spout which via a hose is connected with a urine collection bag. Such external catheters are known in numerous designs and in many cases serve as a satisfactory solution of male incontinence problems. However, the complete
30 envelopment of penis may give rise to trouble, partly because the application which is effected by unrolling the catheter requires a certain length of penis, partly in use due to the fact that the envelopment of the full length of penis with the catheter, which is generally
35 fastened adhesively either by means of a separate

adhesive strip or by means of an internal adhesive layer, involves strain of the skin of penis. Furthermore, the constant humid environment from the delivered urine may cause skin problems, such as
5 allergy and maceration and even ulceration.

In recent years various suggestions have been presented in the prior art concerning the use in a urinary catheter of an inner member or a contact member, which in a position of use is positioned
10 between the surface of the corona and the foreskin of the penis.

Thus, from GB-A-2 075 847 an device is known, which comprises a relatively short funnel-like uridom devise to be placed directly against the corona of the
15 penis and to be kept in place under the foreskin. Around a discharge conduit of the device an external sheathing body is fastened in an inverted position to be brought into engagement with the external side of the foreskin after application of the uridom device to
20 maintain the device in place by means of the sandwich position of the foreskin between the contact member and the external sheathing body.

Another design is disclosed in GB-A-2 126 483, wherein a more safe retainment of the device in the
25 position of use is implemented by use of a tubular urine ducting device, e.g. of silicone rubber, arranged outside the corona in extension thereof, so that a rather severe extension of the foreskin is required to keep the tubular device in place by arrangement of an
30 adhesive strip or strap member on the external side of the foreskin. Evidently, the rather severe extension of the foreskin required to keep the tubular device in place causes considerable discomfort in use.

In EP-B-0 706 355 and EP-B-0 706 356 external
35 urinary catheters are disclosed in which a safe

retainment in the position of use is obtained with considerably less discomfort to the user by means of a short inner contact member designed with improved form stability in its distal end part. Aiming at keeping the
5 contact member safely in place under the foreskin the catheter is provided with a separate substantially bowl-shaped outer holder member displaceably surrounding a discharge conduit of the catheter device. The outer holder member is movable between an
10 application position and a position of use.

Urinary catheters are generally connected via a hose to a urine collection bag. The wearer of the urinary catheter suitably places the urine collection bag in a position lower than the position of the
15 urinary catheter to ensure that the urine effectively is drained off by gravity. To allow free movement of the wearer of the urinary catheter the urine collection bag is generally positioned at a part of the leg. Generally, it is preferred to position the urine
20 collection bag at the shin to drain off urine in a standing as well as a sitting position. Furthermore, this position of the urine collection bag provides for the possibility of hiding it behind a trouser leg.

When using the prior art catheters mentioned
25 above the problem arise, following a discharge of urine, that the unbroken column of urine in the hose give rise to a considerable built-up of sub-pressure at the surface of the corona. The wearer of the urinary catheter is subjected to discomfort, especially on
30 extended exposure to the sub-pressure. Suction marks have been observed on the corona due the exposure to sub-pressure. In severe cases, oedema and subsequent infection has been developed.

It has been suggested to overcome this problem by
35 incorporating a vent or a valve in the urine collection

bag or the lower part of the hose allowing the surrounding air to communicate with the interior of the catheter-hose-bag environment. Reference is made to e.g. US 3,800,857, US 3,835,857, and US 5,622,183.

5 However, the position of a vent or valve in the bag or the lower part of the hose entails the potential risk that urine, when the bag is full or about to be full, will escape the urine collection bag.

Another suggestion is disclosed in US 5,897,540
10 wherein a slit-shaped opening is provided in a condom-like device for drainage of uncontrolled urine release. The opening is provided for ventilation of the space entrapped between the device and the penis and is placed in the position of use at the main body of the
15 penis well behind the corona. The opening is not provided with a filter or similar means. A further suggestion is disclosed in US 4,656,675, which describes a condom-like device for draining off urine. The device is provided with a filter covering a hole
20 positioned at a point close to the source of urine. The filter is capable of passing air but impervious to liquid at relative low pressures. A major drawback of this suggestion is that the filter is placed at an exposed position. The wearer of the device must be
25 careful since the filter easily can be ripped off by abrasion or accident and the urine will tend to be conveyed through the hole in the device and not as intended through the hose.

It is the object of the present invention to
30 avoid all or some of the above discussed problems and drawbacks of the prior art urinary catheters. Especially, it is an object of the present invention to provide a urinary catheter device having an enhanced reliability and durability due to reduced risk of
35 deterioration of a filter means.

Description of the invention

The external urinary catheter device of the kind disclosed in the introduction is, according one aspect of the invention, characterized in that an aperture is provided in a distal part of the contact member or in the discharge conduit; a membrane is fastened to the surface surrounding said aperture, the membrane being capable of selectively passing gases but retaining urine; a shield is at least partly protecting the membrane; and at least one vent is arranged for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

The contact member and optionally also further components of the catheter device according to the invention, such as the discharge conduit and the shield, may be made from any material which is suitable for engagement with the sensitive skin of the corona and the foreskin. Suitable materials include thermoplastic elastomeric materials like styrene-butadiene-styrene (SBS), styrene-isoprene-styrene (SIS), styrene-ethylene/butadiene-styrene (SEBS), styrene-ethylene/propylene-styrene (SEPS), polyethers, polyesters, polyamides, polyurethane or any combination thereof; thermoplastic materials such as plasticized polyvinylchloride (PVC), and polyethylene; or curable elastomeric materials like nitril rubber, chloroprene rubber, natural rubber latex, silicone rubber, liquid silicone, polyisoprene or polyurethane. Preferred materials are SEBS and silicone rubber.

The membrane in the device according to the invention allows gas to pass, whereby it is ensured that the amount of urine discharged from a wearer may be drained to a urine collection bag via a hose without leaving a substantial amount of urine in the hose giving rise to a sub-pressure at the surface of the

corona. The term gas as used in the current context means normally ambient air (a gas mixture of predominately nitrogen, oxygen, and water vapour), however, other gases or compositions of gases may come
5 into play. Following a urine discharge the column of urine in the hose will gradually sink to an equilibrium level such that the pressure in the hose above the urine surface essentially corresponds to the pressure of the surrounding environment. A minor column of urine
10 may be present due to a capillary effect and resistance in the membrane, however without entailing a substantial pressure effect on the surface of the corona.

The aperture provided in the distal part of the
15 contact member or the discharge conduit may have any suitable dimension. The longest diagonal of the aperture may be larger than the diameter of the discharge conduit. However, to avoid a weakening of the discharge conduit, it is preferred that the aperture
20 has a longest diameter less than the diameter of the discharge conduit. A suitable longest diagonal of the aperture is about 0,25 to 0,75 times the inner diameter of the discharge conduit. Preferably the circumference of the aperture is a circle, however other geometrical
25 shapes might be suitable, such as ovals or polygons. Further suitable shapes are constituted by organic shapes. If desired, more than one aperture may be present in the device. The aperture is preferably positioned at a part of the discharge conduit close to
30 the urethral orifice or the distal part of the contact member to obtain sufficient ventilation. A preferred position of the aperture is in the proximal part of the discharge conduit close to the urethral orifice in a position of use.

A membrane is fastened to the surface surrounding the aperture, the membrane being capable of selectively passing gases but retaining urine. During discharge of urine from the urethral orifice the membrane effectively prevent urine from penetration and thus secure a sealed urine flow passage. Following the discharge of urine gas from the surrounding environment is penetrating the pores of the membrane and consequently, the column of urine in the hose is levelled. The membrane suitably maintain the desired selectivity at the relatively low pressures normally expected during use of the catheter device according to the invention. Normally, the water entry pressure of the membrane should be at least 100 mbar above ambient pressure.

The membrane is generally a thin, hydrofobic, porous sheet having the ability of allowing gas, i.e. air, to penetrate but not urine which is retained. A wide range of materials may be used for the membrane. Preferred materials are generally polymers with a low surface tension to water. Examples of suitable polymers are polyethylene, polypropylene, polyurethane, and polytetrafluorethylene (PTFE). Membranes of PTFE is commercially available under various trademarks, e.g. Goretex®. A preferred membrane of polyethylene is commercially available under the trademark Tyvek®.

While the membrane in one aspect of the invention is designed to retain urine at least at the relatively low pressures expected during normal use, it may be desirable, in another aspect of the invention, to use a membrane which at pressures above the level normally expected during use, is adapted to allow the passage of urine to avoid backing up of urine against the penis or ballooning of the foreskin. As an example, a sudden rise in pressure is obtained if the hose is kinked. In

accordance with the second aspect of the invention the membrane is adapted allow the passage of urine at pressures over 80 mbar above ambient pressure, preferably over 100 mbar above ambient pressure.

5 The fastening of the membrane to the surface surrounding the aperture is normally conducted in order to secure a water-tight attachment of the membrane around the aperture. Any suitable method of fastening may be applied, including adhering, rivetting, partly
10 dissolution by solvents, mechanical stress, or welding. Various suitable welding methods exist e.g. thermal, high frequency, ultrasonic, induction, or laser welding. In one aspect of the invention an adhesive is used for adhering the membrane to the surface
15 surrounding the aperture since this method provides a simple and cost-effective way to obtain an effective attachment of the membrane to the surface surrounding the aperture. In another aspect of the invention a rivet is used to fasten the membrane to the surface
20 surrounding the aperture, whereby the membrane is fixed between the male and the female parts of the rivet to providing an effective mechanical attachment of the membrane to the surface surrounding the aperture.

 In still another aspect of the invention a
25 fastening of the membrane to the surface of the aperture is obtained by melting the surface surrounding the aperture to an opposite surface of the membrane by welding or exposure to solvents. It is, in general, preferred to use welding, which includes applying an
30 amount of heat sufficient to melt a part of the plastic material, allowing penetration of the melted plastic material into the pores of the membrane and subsequent allowing solidification of the plastic material. Thus, a simple and reliable way to attach the membrane to the
35 surface around the aperture is obtained. A method

especially suitably for attaching the membrane to the surface surrounding the aperture is ultrasonic or thermal welding.

In some embodiments of the invention it is
5 advantageous to depress or sink an area surrounding the aperture and arrange the membrane in this depression. In such embodiments a space above the external surface of the membrane is generally obtained which allow sufficient ventilation of gases to and from the
10 membrane surface.

In a preferred embodiment of the invention the contact member is integrally connected with the discharge conduit via the opening formed in the distal end section of the contact member. This embodiment
15 makes it possible in a single component of the catheter device to integrate several functions, thus, increasing the industrial processability and securing a sealed urinary flow passage. In some areas of application, it may be useful to connect the discharge conduit to the
20 opening formed in the distal end section of the contact member through a stretchable link to maintain the intimate engagement of the contact member with the penis in a position of use even under tensile load conditions acting on the discharge conduit. The
25 stretchable link may for instance be a bellows-shaped member.

The contact member adapted to be engaged with a penis may be an inner member arrangeable in a position of use between the foreskin and the corona of the
30 penis, an outer member adapted to be positioned on the external face of a penis to provide a sealed contact, and a combination thereof, i.e. an inner member as well as an outer holder member.

In case the contact member is an inner member
35 arrangeable in a position of use between the foreskin

and the corona of a penis it may comprise a shoulder-like ledge at a substantially plane abutment face of the inner member around and substantially perpendicular to the discharge conduit to retain the inner member in
5 contact with the corona solely by means of the foreskin contacting the outer side of the contact member. An inner member of this kind is disclosed in EP 706 355 B1, the entire disclosure thereof being incorporated herein by reference.

10 Another suitable inner member which is arrangeable between the foreskin and the corona of a penis or solely on the corona of a penis e.g. in the absence of foreskin in case of circumcising, comprises a plurality of leaves connected to a housing. The
15 leaves are comprised of a film having an adhesive layer on their interior surface thereof to secure an attachment of the device to the corona of a penis. Preferably, the film as well as the adhesive layer is vapour permeable to increase the comfort of the wearer.
20 An inner member of this kind is disclosed in US 5,263,947 and US 5,827,247, the entire disclosure thereof being incorporated herein by reference.

For fastening the inner member in a position of use, it may be advantageous to provide the catheter
25 device according to the invention with an outer holder member. The outer holder member is preferably formed in a distal end section with an opening for the discharge conduit and arrangeable in said position of use, in a substantially fixed axial position with respect to the
30 discharge conduit for circumferential engagement with the external side of the foreskin.

The outer holder member may be made of any suitable soft elastic, semi-rigid or rigid material such as the plastic materials mentioned above for the
35 contact member or, alternatively, it may be made in the

form of a web of textile material like gauze, hydrocolloide skin adhesive covered with a film, or non-textile material. For improved engagement with the external side of the foreskin the inner engagement
5 surface of the outer holder member may be coated with a layer of a skin-friendly adhesive, e.g. a hydrocolloide skin adhesive. Such an adhesive layer may be dimensioned with controlled adhesive properties and/or be applied in various patterns as known in the art to
10 control the adhesive force. By use of an adhesive layer the length of the outer holder member in the position of use may be reduced to cover an even shorter part of the foreskin in order to increase comfort in connection with wear or removal of the catheter device.

15 The inner member may be permanently connected with a surrounding outer holder member having an opening for the discharge conduit by connection means. In an aspect of the invention said connection means is designed also to comprise the shield for the catheter
20 according to the invention. Thus, the shield is preferably an extended part of the distal end section of the outer holder member. The connection means serving the dual purpose of permanently connecting the contact member with the outer holding member and
25 shielding the membrane is in one aspect of the invention an essentially tubular member arranged around and having walls substantially parallel to the axis of the discharge conduit and integrally connected to the opening of the outer holder member.

30 The preferred materials for the individual parts of the device usually provides for an inherent adherence between the inner face of the tubular member and the outer face of the discharge conduit if the individual parts of the catheter is properly designed.
35 However, the arrangement of the membrane between the

tubular member and the discharge conduit may jeopardise the inherent adherence because the materials for the membrane usually do not show the adherence properties. Therefore, in another aspect of the invention, the
5 inner member is fixed in at least an axial direction relative to the outer holder member by fastening means. As used in the present description and claims, the term fixed is to be understood as an adherence between the tubular member and the discharge conduit which may
10 allow for some flexibility due to the softness and/or shape of the materials used.

In an embodiment of the invention, the outer holder member is fixed in the axial direction by providing the discharge conduit with a ledge above the
15 upper edge of the tubular member. The ledge secures that the outer holder member connected to the tubular member is not moved substantially in the axial direction when the outer holder member in use is pulled back and forward. However, a minor free fit can be
20 allowed if considered expedient, e.g. for customizing the catheter to the anatomy of the individual user. The ledge may extent in the entire circumference of the discharge conduit or a part thereof. In another embodiment the inner face of the tubular member and the
25 outer face of the discharge conduit is provided with corresponding recesses and ledges to secure a locked position in at least the axial direction of the parts of the device. If the tubular member is of a resilient material the fastening may be provided by one or more
30 ledges in the inner face of the tubular member and/or in the outer face of the discharge conduit without corresponding recesses in the counterpart.

The outer holder member and the inner member may be fixed in an axial as well as a rotational direction
35 by fastening means. Suitably, the fixation is provided

by fastening a tubular member integrally connected with the outer holder member to the discharge conduit, which is connected to the inner member. The fastening means may be of any suitable type, especially the fastening
5 may be conducted as described for the fastening of the membrane to the surface surrounding the aperture. In some practical designs of the device the tubular member may be attached to the discharge conduit by thermal or ultrasonic welding. The welding may be conducted in an
10 area in which a part of the membrane is sandwiched between the tubular member and the discharge conduit to provide for the dual function of fastening the membrane to the surface surrounding the aperture and fixing the tubular member to the discharge conduit. The welding
15 may be a point welding. In this case, preferably more than one welding is provided to ensure that the stress delivered to the outer holder member during application or wear of the device is more equally distributed. Preferably 2, 3, or 4 point weldings are provided.

20 In still another embodiment of the invention, the fastening of the outer member relative to the inner member in at least the axial direction can be provided by mechanical means. As an example the area of the tubular member above the transition for the invertible
25 outer holder member may be provided with a collar band or a resilient member which is able to tighten the tubular member to the discharge conduit. The fastening may also be provided by a membrane device. The membrane device may be installed in an aperture through the
30 tubular member as well as the discharge conduit. The membrane device has the ability to retain the tubular member and the discharge device in position relative to each other and to provide for the compulsory membrane. The membrane device may be locked in position in the
35 aperture by any suitable fastening means. As an example

the membrane device may be formed as a rivet or the device may be adhered to the surface surrounding the aperture.

The contact member adapted to be in engagement
5 with the penis, may in an aspect of the invention be adapted to be positioned on the external face of a penis to providing a sealed contact. To ensure an effective sealing between the contact member and the penis the contact member is suitably of a length
10 covering the extreme portion, e.g. the foreskin or the corona, as well as the main body of the penis. An aperture can suitably be provided in a proximal part of the discharge conduit and covered with a membrane. A shield may be provided over the membrane as a separate
15 or integral tubular member with an internal diameter substantially corresponding to or slightly smaller than the external diameter of the discharge conduit to fix the membrane. A stiffening member may be arranged inside the discharge conduit to provide a suitable
20 abutment for the tubular member. The tubular member can be provided with one or more flaps for facilitating the removal of the device.

The urinary catheter of the invention comprises at least one vent which is arranged for allowing the
25 gases, e.g. air, to be in substantially unhindered contact with the external surface of the membrane. The vent may be provided in any suitable way to ensure that the gases virtually unhindered can be conveyed from or to at least a part of the surface of the membrane.
30 Thus, vents may be provided in the shield, the discharge conduit or both. Alternatively, the vent may be one or more hollow fibres or the like provided between the inner face of the shield and the outer surface of the discharge conduit to allow gas

communication between the external face of the membrane and the surrounding environment.

In an aspect of the invention the vent is a single aperture provided in the shield. The aperture in
5 the shield covers preferably the entire active membrane area to allow sufficient ventilation, however, especially in embodiments where the inner face of the shield is not in direct contact with the membrane, it may be desirable to provide the catheter according to
10 the invention with an aperture smaller than the active membrane area to obtain a extended protection of the membrane.

In another aspect of the invention, the shield is provided with a plurality of apertures for ventilation.
15 This aspect is of particular interest when a space above the external surface of the membrane is provide because the entire membrane area may be active. A space above the external membrane may be provided e.g. by fastening the membrane with a rivet or by attaching the
20 membrane in a depression of the external surface of the discharge conduit. A plurality of relatively small apertures relative to a single larger aperture is regarded to be more effective for protecting the membrane since sharp or pointed devices to a larger
25 extent is prevented from coming into intimate contact with the membrane from the outside of the catheter device.

A vent passage may also be provided using one or more tracks for channelling the gases to or from the
30 external surface of the membrane to the surrounding environment. In particular, one or more track(s) may be provided in the inner face of the shield to establish a vent passage from the external surface of the membrane to the exterior of the catheter device.

In one aspect of the invention a plurality of tracks substantially parallel to the axis of the discharge conduit are formed in the inner face of the shield in a part or the entire circumference thereof
5 establishing a vent passage from the external surface of the membrane to the exterior of the catheter device. The aspect of using tracks in the entire circumference of the inner surface of the shield could be advantageous from a production point of view as the
10 assembling of the catheter is independent of the relative position of the shield and the membrane due to the rotational symmetry of the shield.

The depression (17) receiving the membrane may be provided with one or more depressed track(s) extending
15 in a distal direction beyond the edge of the shield, said track(s) establishing a vent passage from the external surface of the membrane to the exterior of the catheter device. This alternative is attractive from a production point of view since the mould in which the
20 device is formed, may be designed to provide an impression in the catheter part, said impression having the dual purpose of receiving the membrane and establishing an effective ventilation through the track(s). Moreover, the shield may have a tubular
25 rotational symmetrical shape making it possible to assemble the catheter without observing the relative position of the shield and the membrane.

To obtain a large cross-section of the vent(s) one or more track(s) may be provided in the discharge
30 conduit as well as the inner face of the shield, said tracks in common providing one or more channels for ventilation.

The track(s) provided in the discharge conduit and/or the inner face of the shield may have any
35 suitable shape. Normally, the tracks are parallel to

the axis of the discharge conduit to obtain the shortest channel. Other shapes may be considered to obtain specific properties of the catheter. As an example, the track may be provided with one or more
5 bends to trap dust and to avoid penetration of pointed devices. As another example, tracks on the discharge conduit may be thread-like, whereby the gas is conducted around the axis of the discharge conduit.

The invention also pertains to a process for
10 production of an external urinary catheter device for the relief of male urinary incontinence, which comprises the steps of

providing a catheter part comprising a contact member which is adapted to be engaged with a penis; an
15 opening formed in a distal end section of the contact member and positioned substantially opposite the urethral orifice in the position of use; and a discharge conduit connected with the opening to provide a sealed urine flow passage extending in a substantial
20 axial direction towards the exterior of the catheter device,

providing an aperture in a distal part of the contact member or in the discharge conduit,

fastening a membrane to the surface surrounding
25 said aperture, the membrane being capable of selectively passing gases but retaining urine,

providing a shield to protect the membrane, and
arranging at least one vent for allowing gases to
be in substantially unhindered contact with the
30 external surface of the membrane.

The catheter part comprising the contact member, opening and discharge conduit may be assembled of individual members or be produced in one piece. It is preferred to produce the catheter part in one piece due
35 to the process economy by integrally connecting the

contact member to the discharge conduit via the opening formed in the distal end section of the contact member. The catheter part may suitably be produced by plastic injection moulding using the polymer materials previously mentioned.

The aperture may be provided in any suitable way ensuring that gases substantially unhindered can communicate with the internal face of the membrane. In case the catheter part is produced in one piece by plastic injection moulding the mould is suitably adapted to provide the aperture during manufacture of the catheter part.

The membrane fastened to the surface surrounding the aperture is suitably fastened such that it is secured that a water-proof attachment is obtained. The fastening procedure may be any suitable method securing a water-proof attachment, including adhering, rivetting, partly dissolution by solvents, and welding. A preferred method of attachment comprises melting the surface surrounding the aperture to an opposite surface of the membrane. A preferred method of fastening the membrane to the surface surrounding the aperture is conducted by welding. Various welding methods are suitable, including ultrasonic, high frequency, induction, laser, and thermal welding. It is in general preferred to conduct the fastening by ultrasonic or thermal welding.

In an aspect of the invention according to the above process it pertains to the step of further providing the catheter part with an outer holder member for fastening the contact member in the position of use, wherein the outer holder member is formed in a distal end section with an opening for said discharge conduit and arrangeable in a position of use, in a substantially fixed axial position with respect to the

discharge conduit for circumferential engagement with the external side of the foreskin.

The invention also provides a dip forming process for manufacture of an external urinary catheter device
5 for the relief of male urinary incontinence, comprising the steps of

- a) providing a liquid polymer solution or emulsion comprising a polymer and a solvent or a diluent in an amount sufficient for permitting dip
10 forming,
 - b) providing a form having a first part for forming a contact member adapted to engage with a penis, a second part for forming an opening in the distal end section of the contact member and a
15 third part for forming a discharge conduit, the first, second and third part being integrally connected,
 - c) dipping said form in said solution or emulsion,
 - d) removing the form from the solution or emulsion,
 - 20 e) allowing the solvent or the diluent to evaporate, and
 - f) optionally, repeating the steps c), d), and e) until the device has attained the desired wall-thickness, wherein
- 25 a membrane, capable of selectively passing gases but retaining urine, is arranged at the part of the form for forming the distal part of the contact member or the third part of the form forming the discharge conduit prior to dipping according to step c) or during
30 evaporation according to step e).

During the manufacture it should be ensured that the polymer film resulting from step e) is prevented from coming into contact with the internal and the external face of the membrane or the polymer film is
35 only releaseably attached to the membrane surface to

allow the provision of an aperture and a vent on the internal and the external face of the membrane, respectively.

The liquid polymer solution or emulsion for performing the dip forming process according to the invention may comprise any polymer material which is suitable for engagement with the sensitive skin of the penis. Examples of suitable polymers include SBS, SIS, SEBS, natural rubber latex, SEPS, polyisoprene, polychloroprene, nitril rubber, silicone rubber, curable liquid silicone, polyurethane and any combination and quality thereof.

In the instance the liquid polymer is a solution, the solvent for dissolving the polymer is suitably an inert solvent of an aromatic or aliphatic nature or a combination thereof, however any solvent able to create a stable solution may be applied. The amount of solvent is appropriately sufficient for obtaining a solution without precipitations of polymer. In general the amount of solvent is higher than the minimum required for obtaining a solution to obtain a viscosity suitable for dip forming. A preferred amount of solvent is from 400 to 1200 % by weight, based on the amount of polymer.

When the liquid polymer is an emulsion, the polymer is diluted with a suitable diluent. Preferably, the liquid polymer also contains an emulsifying agent to stabilize the emulsion. A suitable diluent is water. It is generally preferred that the emulsion contains sufficient diluent so as to obtain a viscosity of 100 cp to 1000 cp. The emulsion may optionally comprise a suitable coagulation agent, such as $\text{Ca}(\text{NO}_3)_2$ or CaCl_2 , to obtain an increased wall-thickness. Furthermore, the emulsion may contain a curing agent. The curing agent may e.g. be activated by heat, moisture, ultra violet

light, or electron beam. For certain kinds of polymers, e.g. silicone, it is possible to prepare a liquid polymer suitable for dip forming without the usage of a diluent.

5 The form for dipping into the polymer solution or emulsion is appropriately adapted for receiving a membrane in the part of the form for forming the distal part of the contact member and/or in the third part of the form for forming the discharge conduit. The
10 membrane may according to the invention be provided prior to dipping or during the evaporation.

 In case the membrane is provided prior to dipping suitable means is provided for securing that the final device is not provided with a polymer film resulting
15 from the evaporation step e). Various means exist, including providing the intended active membrane area with a coating which repels the liquid polymer, using a material for the membrane which in itself repels the polymer solution, covering the intended active membrane
20 area with a removable item, and removing a releaseable attached polymer film from the membrane surface with suitable means.

 A preferred method of avoiding a polymer film is to press a central part of the membrane against the
25 form from the external side of the membrane by a suitable tool which covers the part of the membrane intended to be the active membrane area. While the central part of the membrane area is pressed against the form, edges and corners of the membrane sheet is
30 embedded in the polymer matrix during the dip forming. It may be advantageous to provide the membrane on a suitable carrier, wherein the carrier material surrounds the active membrane area and is adapted to be able to anchor the membrane in the polymer matrix.
35 Thus, the membrane is shielded as the edges and corners

is embedded in the polymer matrix, whereby the risk of deteriorating the membrane during use is reduced. Furthermore, a vent passage is provided by the pressing tool.

5 It may be preferred to attach the membrane prior to the dipping according to step c) to a raised platform to increase the anchoring effect of the material surrounding the active membrane area and to provide for an aperture having a less tendency to be occluded by
10 the polymer solution during dipping. Preferably, the membrane is kept on the platform during the dip forming procedure by a suitable pressing means, which may allow for the production of a vent passage.

 The membrane may also be provided prior to or
15 during evaporation according to step e) or curing if a curing agent is provided in the polymer liquid. Suitably, a sufficient amount of solvent is allowed to evaporate to essentially preserve the dimension stability of an aperture being provided in the polymer
20 film. A membrane sheet comprising an area intended to be active in the final device is arranged such that it covers the aperture and the area of the membrane surrounding the area intended to be active is attached to the area surrounding the aperture. The attachment can
25 be effected in any appropriate way, e.g. by pressing the surrounding area of the membrane into the still fluid polymer matrix or adhering the surrounding area of the membrane to the area surrounding the aperture by any suitable means following evaporation of an
30 essential amount of the solvent. A shield may be provided aiming at protecting the membrane by a repetition of the steps c), d) and e). It must be secured during the repetition that at least one vent is arranged for allowing gases to be in substantially
35 unhindered contact with the external surface of the

membrane. The means for providing the vent can be similar to the means for avoiding the polymer film resulting from the evaporation step e), as discussed above. A preferred method is to press a tool against a
5 central part of the external surface of the membrane to protect the intended active membrane area against coming into contact with the polymer solution.

The invention also pertains to a process for manufacture of an external urinary catheter device for
10 the relief of male urinary incontinence, comprising the steps of

providing a mould comprising a matrix and a core for plastic injection moulding, wherein the cavity defined by the matrix and the core comprises a first
15 part for forming a contact member adapted to engage with a penis, a second part for forming an opening in the distal end section of the contact member and a third part for forming a discharge conduit, the first, second and third part being integrally connected,

20 injecting a liquid plastic material into the cavity of the mould,

solidification of the liquid plastic material,
and

recovering the moulded device from the mould,
25 wherein a membrane capable of selectively passing gases but retaining urine is arranged at the part of the cavity for forming the distal part of the contact member or the third part of the cavity for forming the discharge conduit.

30 The liquid plastic material for the injection moulding process is typically a melted thermoplastic material, which is solid at normal ambient temperatures or a curable liquid polymeric material such as liquid silicone.

During the injection moulding procedure according to the above process it should be ensured that neither the internal face nor the external face of the membrane is occluded by plastic material. In an aspect of the process of the invention the internal face of the membrane is covering an aperture and/or the external face of the membrane is protected with a shield having a vent.

A vent allowing gases to communicate with the external face of the membrane may be provided by pressing a central part of the membrane against the core by a suitable tool from the matrix side. In addition or alternatively, an aperture allowing urine and gas to communicate with the interior of the membrane surface may be provided by pressing a central part of the membrane against the matrix with a suitable tool from the core side. Suitably, the part of the pressing tool which faces the membrane has an area which may cover a part of the membrane intended to be the active membrane area in the final device. The part of the membrane not pressed with the tool is embedded in the polymer matrix during the plastic injection moulding and provides for an attachment of the membrane to the polymer matrix. To ensure a proper attachment, the membrane may be provided on a carrier having properties which effectively anchor the membrane to the polymer matrix.

It may be advantageous to design the mould with a core and/or a matrix which comprise a raised platform as the tool for pressing the membrane against the matrix and/or the core. The embodiment in which the core as well as the matrix comprise a raised platform, the membrane is arranged within the cavity by pressing the two raised platforms against the membrane. This embodiment ensures the production of a device wherein

an aperture as well as a vent is provided. Furthermore, the membrane is shielded from deterioration due to the embedment of the edges and corners of the membrane sheet.

5

Brief description of the drawings

Fig. 1 shows a sectional view of an embodiment of the invention with an outer holder member in an application position.

10 Fig. 2 shows a sectional view of the embodiment depicted in Fig. 1 with the outer holder member in a position of use.

Fig. 3 shows an enlarged view of the embodiment disclosed in Figs. 1 and 2 with the layers in the
15 vicinity of the membrane partly broken away.

Fig. 4 shows a detail of a second embodiment of the invention with the shield partly broken away.

Fig. 5 shows a sectional view of the detail of the second embodiment on Fig. 4. The section is
20 indicated by V on Fig. 4.

Fig. 6 shows a front view of a detail of a third embodiment of the invention.

Fig. 7 shows a sectional view of the detail of the embodiment of Fig. 6. The section is indicated by
25 VII on Fig. 6.

Fig. 8 shows a sectional view of a detail of the embodiment shown on Figs. 6 and 7. The section is indicated by VIII on Fig. 6.

Fig. 9 shows a front view of a detail of a fourth
30 embodiment of the invention.

Fig. 10 shows a sectional view of a detail of the embodiment indicated on Fig. 9. The section is shown by X on Fig. 9.

Fig. 11 shows a sectional view of a detail of the embodiment shown on Figs. 9 and 10. The section is prepared as indicated by XI on Fig. 9.

Fig. 12 shows a detail of a front view of a fifth embodiment of the invention.

Fig. 13 shows a sectional view of a detail of the embodiment shown on Fig. 12. The section is indicated on Fig. 12 at XIII.

Fig. 14 shows a detail of a front view of an embodiment with a ledge that provides for the fastening of the tubular member in an axial direction.

Fig. 15 shows a sectional view of a detail on the embodiment shown on Fig. 14.

Fig. 16 shows a detail of a front view of an embodiment wherein the fastening is provided by a point welding.

Fig. 17 shows a detail in perspective, wherein vents are provided in the interior of the face of the tubular member.

Fig. 18 shows a detail of a front view, wherein a membrane device fastens the tubular member to the discharge conduit.

Fig. 19 shows a sectional view of the embodiment shown on Fig. 18. The section is indicated on Fig. 18 at XIX.

Detailed description of the invention

The catheter device shown in Figs. 1, 2, and 3 comprises a contact member 1 which is formed with an opening 5 which in a position of use as shown in Fig. 2 is situated opposite the urethral orifice in the corona 3 of a penis 4. At the opening 5, the distal end section 6 joints discharge conduit 7 by which the catheter may be connected e.g. with a hose member, through which discharges of urine may flow from the

contact member into a collection bag not illustrated. Thereby a sealed urine flow passage is provided to extend, from the inner side of the contact member 1 facing the urethral orifice, in a substantially axial direction towards the exterior of the catheter device.

As shown in Fig. 2 the contact member 1 is formed to be placed in use under the foreskin 2 of the penis 4 in contact with the corona 3.

In the distal end section 6 around the discharge conduit 7 the contact member 1 is designed with increased form stability so as to form a shoulder-like ledge 13 having e.g. a substantially flat end face so that in use the contact member 1 is retained by the foreskin 2.

To provide an improved sealing effect against the corona 3 the inner side of the contact member 1 is coated with a layer 19 of a skin-friendly adhesive as used for medical devices intended to be in contact with sensitive skin tissue.

In the embodiment shown, the discharge conduit 7 and the contact member 1 are connected with a surrounding outer holder member 12 having an opening for the discharge conduit 7 via the tubular connection member 20. As shown in Figs 1 and 2, the outer holder member 12 is formed as an invertible substantially bowl-shaped member, which from the inverted application position i Fig. 1 can be brought into the position of use by tilting it around the transition to the connection member 20. An annular applicator not shown on the figures for engagement with the extreme portions of the outer holder member 12 may be used to invert the outer holder member 12 from an application position depicted in Fig. 1 to a position of use depicted in Fig. 2. Such an annular applicator will be effective to facilitate accurate positioning of the contact member 1

relative to the corona during application of the catheter device.

The inner engagement surface of the outer holder member 12 is partly or totally coated with a layer 21 of a skin-friendly adhesive for improved engagement with the external surface of the foreskin 2. The provision of the adhesive is not compulsory, however, and may be dispensed with, since a sufficient holding force may be obtained by other means, e.g. dimensioning of the outer holder member with a length so as to cover, in the position of use, the entire external side of the foreskin surrounding the corona.

In order to facilitate removal of the catheter device after use the distal end of the tubular connection member 20 is formed with a projecting flap 22, which may serve as a grip which can be operated to remove the outer holder member 12 by pulling back the projecting flap 22 in a direction towards the inverted position, from which the holder member was originally applied.

As shown in detail on Fig. 3 an aperture 8 is provided in a proximal part of the discharge conduit 7 relatively close to the urethral orifice in a position of use. A membrane 9 capable of selectively passing gases but retaining urine, is covering the aperture 8 and attached to the area of the discharge conduit surrounding the aperture 8 via an adhesive 23. The membrane 9 is in turn covered with a shield 10, which is a part of the tubular connection member 20, for providing protection of the membrane. A single vent 11 is provided in the shield 10 for allowing gases to be in substantially unhindered contact with the external surface of the membrane. The vent 11 in the shield 10 has a dimension corresponding to the dimension of the aperture 8 allowing the active membrane area virtually

unhindered to communicate with the surrounding environment, while preventing the edges and corners of the membrane to be exposed to mechanical wear, thus reducing the risk of deterioration of the membrane.

5 Figs. 4 and 5 show an embodiment of the invention using a rivet 24 to fasten the membrane to an area of the discharge conduit surrounding the aperture. The membrane is fastened to the orifice of the rivet by clamping between the male 25 and the female 26 part of
10 the rivet 24. The male part 25 of the rivet 24 shown on Fig. 5 provides a raised platform for the shield 10, whereby an increased space between the external side of the membrane and the shield is formed. The shield is provided with a plurality of apertures 14 as vents
15 allowing a virtually unimpeded diffusion of gases between the space above the membrane surface and the surrounding environment.

Figs. 6, 7, and 8 show an embodiment of the invention where the membrane is depressed in the
20 surface of the discharge conduit 7 and tracks 18 are provided for ventilation. A hand-like depression is cast in the outer face of the discharge conduit, said depression comprising a carpus 27 and three fingers 18 extending in a distal direction. The carpus 27 of the
25 hand-like depression is provided with a membrane 9 attached to the area around the aperture by welding. A tubular shield 10 is covering the carpus 27 and a part of the fingers 18 but not the fingertips. During use of the catheter device of the invention air may be vented
30 through the openings at the fingertips and conducted via the fingers covered by the shield 10 to the external surface of the membrane 9.

Figs. 9, 10, and 11 disclose an embodiment of the invention where the membrane is depressed in the
35 surface of the discharge conduit and tracks in the

inner face of the shield provides for the ventilation. A circular depression 28 is formed in the discharge conduit 7 in an area around the circular aperture 8. A membrane 9 is attached to the depressed area around the aperture by welding. A tubular shield 10 is covering the depression and extends over the circumference thereof. Three tracks 29 are provided in the inner face of the shield 10 to establish a vent passage from the external surface of the membrane to the exterior of the catheter device. In operation, air is sucked in at the opening formed by the tracks 29 in the edge of the shield 10. The air is subsequently conducted through the tracks to the external surface of the membrane.

Figs. 12 and 13 show an embodiment of the invention, in which the vent passage is provided by a plurality of tracks formed in the inner face of the shield. The membrane 9 is provided and covers the aperture as explained for the embodiment according to Figs. 1, 2, and 3. A tubular shield 10 is surrounding the part of the discharge conduit harbouring the aperture covered with the membrane. The edge of the tubular shield extent above the upper edge of the membrane. A plurality of tracks 30 substantially parallel to the axis of the discharge conduit are formed in the inner face of the shield in the entire circumference thereof. In operation, air is sucked in at the openings formed by the tracks 30 in the edge of the shield 10 and subsequently conveyed to the external surface of the membrane. Thus, the tracks 30 establishes a vent passage allowing air from the exterior of the catheter to come into contact with the surface of the membrane.

Fig. 14 and 15 show an embodiment of the invention, in which the outer holder member 12 impeded in moving in an axial direction when stressed with a

forward or backward pulling force. When the outer holder member is pulled forward, that is towards the penis e.g. during application, the outer holder member is halted in an axial movement by the contact member 5 and during use the tubular connection member connected to the outer holder member is halted from performing an axial movement by the ledge provided on the discharge conduit just above the upper edge of the tubular member. This embodiment is of special interest when the 10 adherence between the inner face of the tubular connection member and the external face of the proximal part of the discharge tube is absent or reduced, e.g. due to the lack or reduced inherent adherence between the membrane and the inner face of the tubular 15 connection member.

In the embodiment shown in Fig. 16 the outer holder member and the inner member is fixed in an axial as well as a rotational direction by a ultra sonic point welding 32. The point welding is conducted in an 20 area wherein the membrane 9 is not sandwiched. Another point welding not shown on the figure is provided on the diagonally opposed face of the device. The embodiment is provided with a single projecting flap 22.

25 Fig. 17 discloses a detail of an embodiment where the membrane is shielded by a tubular member covering the entire surface of the membrane. For allowing gases to communicate with the exterior face of the membrane, tracks are provided in the inner face of the tubular 30 member.

Fig. 18 and Fig. 19 depict an embodiment where the tubular connection member is fastened to the discharge conduit using a membrane device 34. The membrane device comprises a housing and a membrane 9, 35 the membrane being supported by corrugations 35. The

corrugations provide for tracks which are extended in a part of the discharge conduit. The membrane device is placed in an aperture going through the tubular connection member as well as the proximal part of the
5 discharge conduit securing a locked position in an axial and a rotational direction of the outer holder member relative to the contact member. Finger-like channels 18 are formed in the external face of the discharge conduit to provide for gas communication
10 between the external surface of the membrane and the surrounding air. The finger-like channels are partly covered with the tubular connection member, however, the finger tips are not covered and secure a proper ventilation.

15 While in the foregoing, embodiments of the invention have been disclosed in considerable detail for purpose of illustration, it will be understood by those skilled in the art that many of these details may be varied without departing from the spirit and scope
20 of the invention.

C L A I M S

1. An external urinary catheter device for the relief of male urinary incontinence, comprising

a contact member (1) which is adapted to be
5 engaged with at least the extreme portion of a penis (4),

an opening (5) formed in a distal end section (6) of the contact member (1) and positioned substantially opposite the urethral orifice in the position of use,

10 a discharge conduit (7) connected with the opening (5) to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device,

wherein,

15 an aperture (8) is provided in a distal part of the contact member (1) or in the discharge conduit (7),

a membrane (9) is fastened to the surface surrounding said aperture (8), the membrane being capable of selectively passing gases but retaining
20 urine,

a shield (10) is at least partly protecting the membrane, and

at least one vent (11) is arranged for allowing gases to be in substantially unhindered contact with
25 the external surface of the membrane.

2. The external urinary catheter device according to claim 1, wherein the contact member is integrally connected with the discharge conduit via the opening formed in the distal end section of the contact member.

30 3. The external urinary catheter device according to claim 1 or 2, wherein the contact member (1) is an inner member arrangeable, in a position of use, between the foreskin (2) and the corona (3) of a penis (4),

4. The external urinary catheter device according
35 to claim 3, wherein the inner member comprises a

shoulder-like ledge (13) at a substantially plane abutment face of the contact member around and substantially perpendicular to the discharge conduit.

5 5. The external urinary catheter device according to claim 3, wherein the inner member comprises a plurality of leaves comprised of a film having an adhesive layer on the interior surface thereof to secure an attachment of the device to the corona of a penis.

10 6. The external urinary catheter device according to any of the preceding claims further comprising an outer holder member (12) for fastening the contact member in the position of use, wherein the outer holder member is formed in a distal end section with an
15 opening for said discharge conduit and arrangeable in said position of use, in a substantially fixed axial position with respect to the discharge conduit for circumferential engagement with the external side of the foreskin.

20 7. The external urinary catheter device according to claim 6, wherein the inner member is fixed in at least an axial direction relative to the outer holder member by fastening means.

25 8. The external urinary catheter device according to claim 7, wherein the fixation is provided by fastening a tubular member integrally connected with the outer holder member to the proximal part of the discharge conduit or the distal part of the contact member.

30 9. The external urinary catheter device according to any of the claims 6 to 8, wherein the fixation is provided by thermal or ultrasonic welding.

35 10. A process for production of an external urinary catheter device for the relief of male urinary incontinence, which comprises the steps of:

providing a catheter part comprising a contact member (1) which is adapted to be engaged with a penis (4); an opening (5) formed in a distal end section (6) of the contact member (1) and positioned substantially
5 opposite the urethral orifice in the position of use; and a discharge conduit (7) connected with the opening (5) to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device,

10 providing an aperture (8) in a distal part of the contact member (1) or in the discharge conduit (7),

fastening a membrane to the surface surrounding said aperture (8), the membrane being capable of selectively passing gases but retaining urine,

15 providing a shield (10) to protect the membrane, and

arranging at least one vent (11) for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

20 11. The process according to claim 10, wherein the contact member is integrally connected to the discharge conduit via the opening formed in the distal end section of the contact member.

12. The process according to claim 10 or 11
25 further comprising the step of providing the catheter part with an outer holder member (12) for fastening the contact member in the position of use, wherein the outer holder member is formed in a distal end section with an opening for said discharge conduit and
30 arrangeable in a position of use, in a substantially fixed axial position with respect to the discharge conduit for circumferential engagement with the external side of the foreskin.

13. A process for manufacture of an external urinary catheter device for the relief of male urinary incontinence, comprising the steps

- 5 a) providing a liquid polymer solution or emulsion comprising a polymer and a solvent or a diluent in an amount sufficient for permitting dip forming,
 - 10 b) providing a form having a first part for forming a contact member adapted to engage with a penis, a second part for forming an opening in the distal end section of the contact member and a third part for forming a discharge conduit, the first, second and third part being integrally connected,
 - 15 c) dipping said form in said solution or emulsion,
 - d) removing the form from the solution or emulsion,
 - e) allowing the solvent or the diluent to evaporate, and
 - 20 f) optionally, repeating the steps c), d), and e) until the device has attained the desired wall-thickness, wherein
- a membrane, capable of selectively passing gases but retaining urine, is arranged at the part of the form for forming the distal part of the contact member or at
- 25 the third part of the form for forming the discharge conduit prior to dipping according to step c) or during evaporation according to step e).

14. A device obtainable by the process according to claim 13.

30 15. A process for manufacture of an external urinary catheter device for the relief of male urinary incontinence, comprising the steps of

providing a mould comprising a matrix and a core
for plastic injection moulding, wherein the cavity
35 defined by the matrix and the core comprises a first

part for forming a contact member adapted to engage with a penis, a second part for forming an opening in the distal end section of the contact member and a third part for forming a discharge conduit, the first,
5 second and third part being integrally connected,

injecting a liquid plastic material into the cavity of the mould,

solidification of the liquid plastic material,

and

10 recovering the moulded device from the mould,

wherein a membrane capable of selectively passing gases but retaining urine is arranged at the part of the cavity for forming the distal part of the contact member or the third part of the cavity for forming the
15 discharge conduit.

16. A device obtainable by the process according to claim 12.

17. A kit for relief of male urinary incontinence comprising

20 an external urinary catheter device according to any of the claims 1 to 6, 14, or 16,

a bag for collection of urine discharged from the catheter device, and

a hose member connecting the catheter device and
25 the bag.

18. A use of the external urinary catheter device according to any of the claims 1 to 6, 14, or 16, or the kit according to claim 17 for relief of male urinary incontinence.

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An external urinary catheter device for the relief of
5 male urinary incontinence.

A B S T R A C T

An external urinary catheter for the relief of male
urinary incontinence is provided. The catheter
10 comprises a contact member which is adapted to be
engaged with at least the extreme portion of a penis,
said contact member being connected to a discharge
conduit via an opening in the distal end section of the
contact member. The catheter is provided with an
15 aperture. A membrane, which is capable of selectively
passing gases but retaining urine, is fastened to the
surface surrounding the aperture. The membrane is at
least partly protected by a shield. At least one vent
for allowing gases to be in substantially unhindered
20 contact with the external surface of the membrane is
arranged in the catheter.

(Fig. 1)

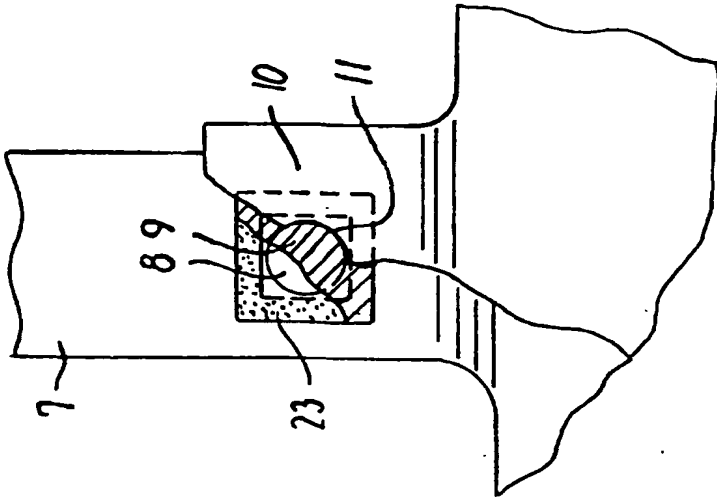


FIG. 3

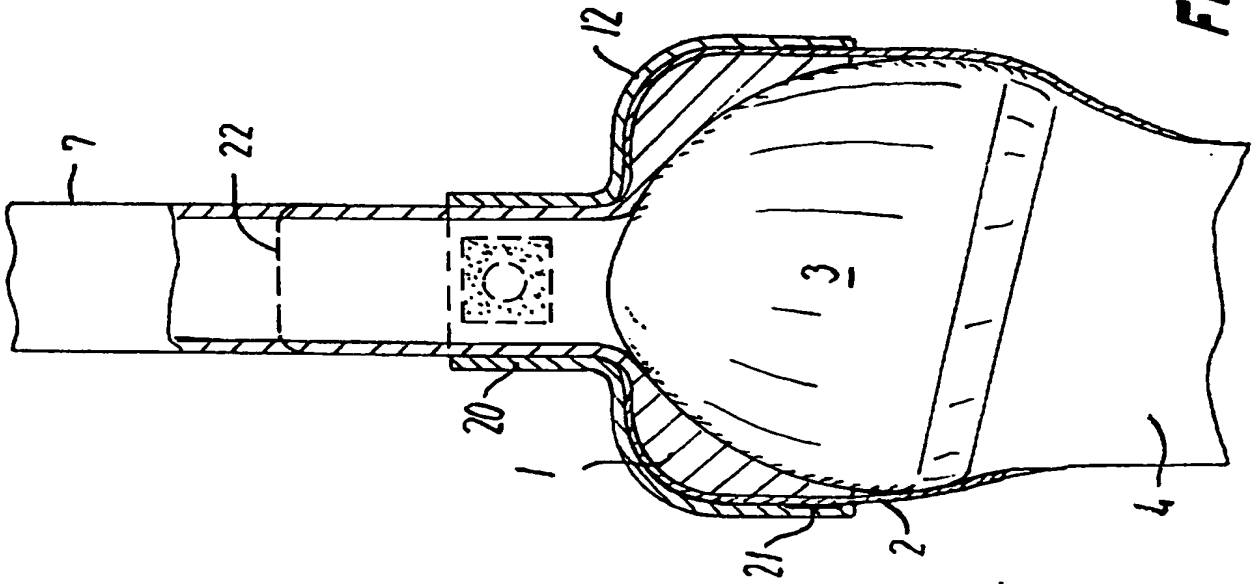


FIG. 2

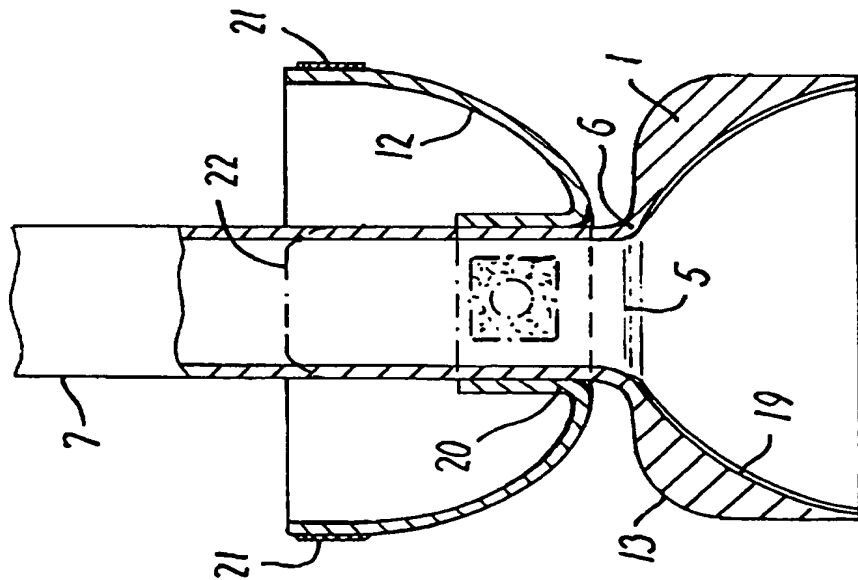
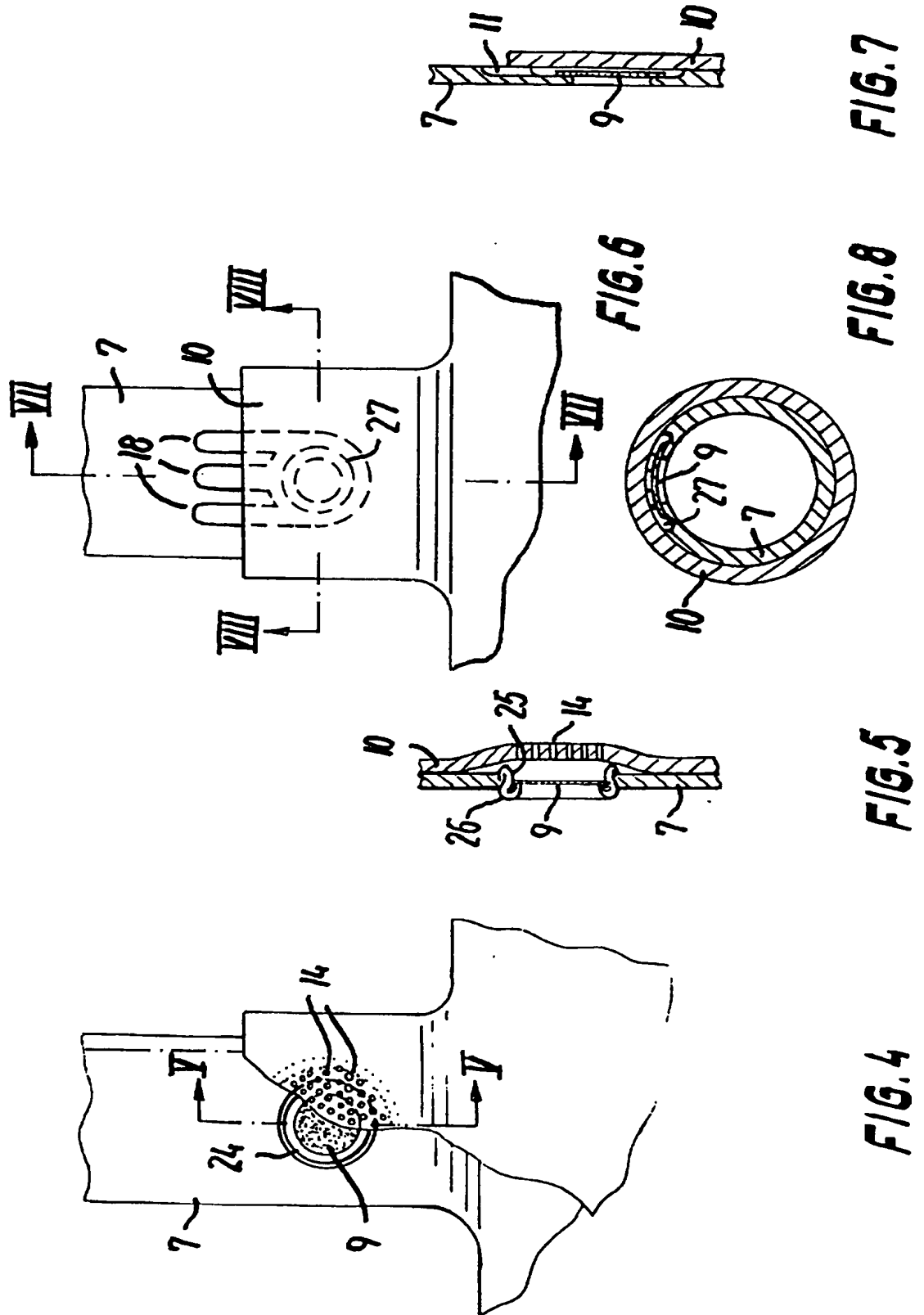


FIG. 1

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Modtaget



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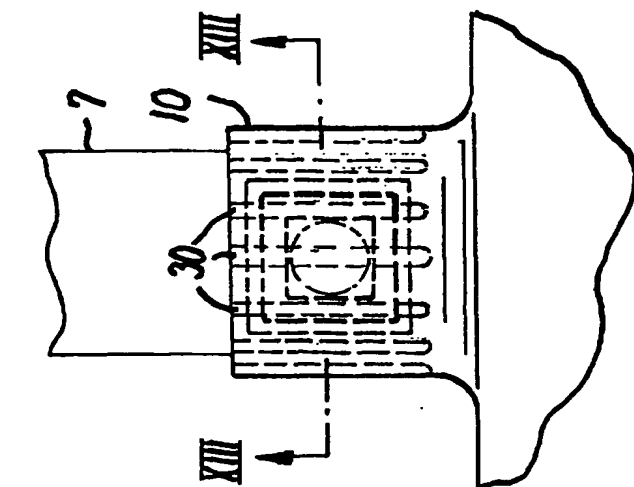


FIG. 12

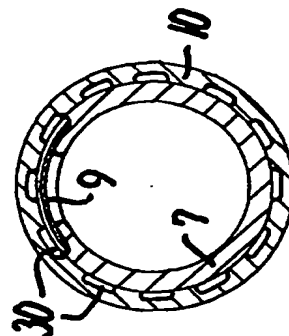


FIG. 13

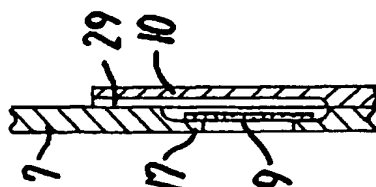


FIG. 10

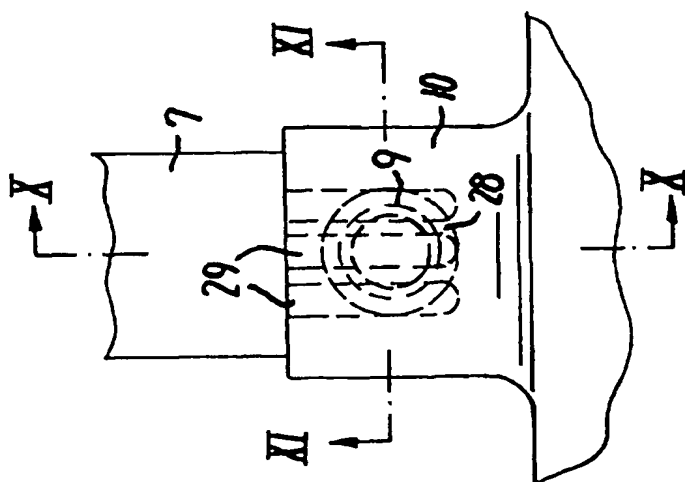


FIG. 9

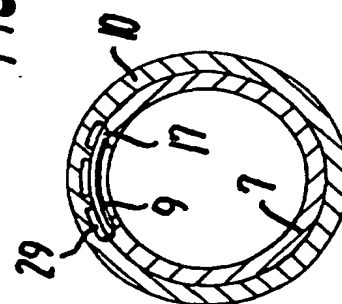


FIG. 11

Patent- og
Varemærkestyrelsen

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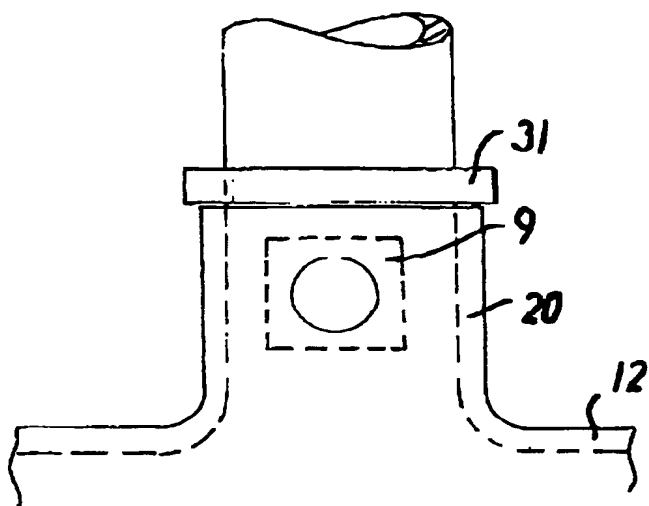


FIG. 14

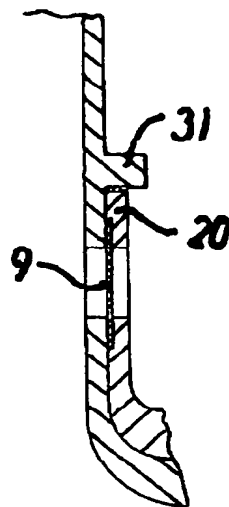


FIG. 15

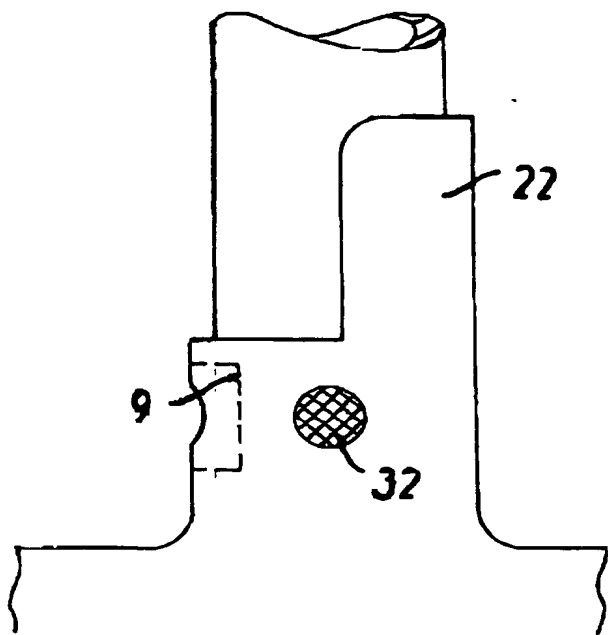


FIG. 16

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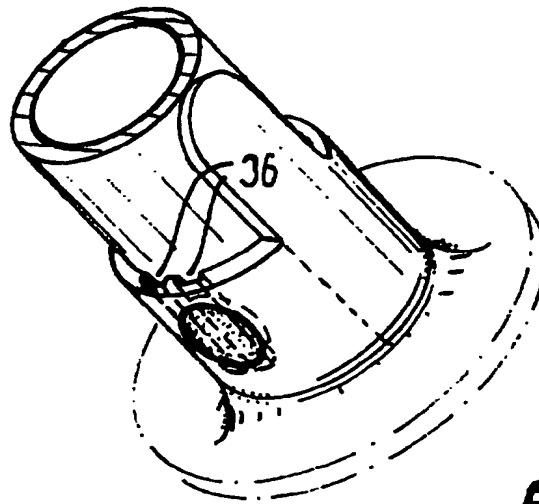


FIG. 17

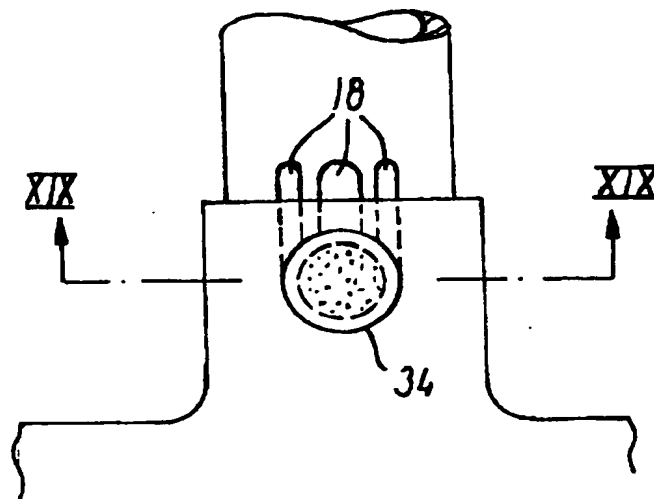


FIG. 18

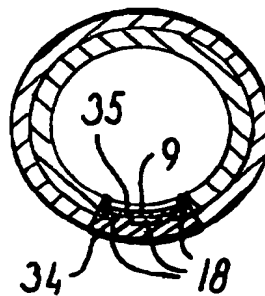


FIG. 19